TESTIMONY BEFORE THE

SUBCOMMITTEE ON COMMERCE, TRADE, AND CONSUMER PROTECTION OF THE HOUSE COMMITTEE ON ENERGY AND COMMERCE

HEARING ON

THE PROTECTING CONSUMER ACCESS TO GENERIC DRUGS ACT OF 2009

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Mr. Chairman and Members of the Committee, I am Joanne Handy, a member of AARP's Board of Directors. On behalf of our more than 40 million members, thank you for the opportunity to testify today in support the "Protecting Consumer Access to Generic Drugs Act of 2009" (HR 1706). This legislation seeks to prevent patent settlements in which the generic pharmaceutical manufacturer receives anything of value in exchange for agreeing not to research, develop, manufacture, market, or sell its product (what some refer to as "reverse payments" or "exclusion payments").

Generic Drugs Provide and Affordable Prescription Drug Alternative

Older Americans use prescription drugs more than any other segment of the U.S. population. Unfortunately, costs for branded drug products continue to rise at rates that far exceed inflation, causing a strain on the budgets of consumers and other health care payers.

A recent AARP Public Policy Institute study revealed that, on average, pharmaceutical manufacturer prices for the 220 brand name drugs most widely used by Medicare beneficiaries have increased substantially higher since the implementation of Medicare Part D. In 2007, the average rate of increase in manufacturer prices for these widely used brand name drugs was more than two and one-half times the rate of general inflation.[1] For the 169 brand name drugs that have been on the market since 2002, this translates into a cumulative average price increase of 50.4 percent, over two and one-half times the general inflation rate of 19.0 percent over the same period.[2]

[1] David J. Gross, Stephen W. Schondelmeyer, and Leigh Purvis, Rx Watchdog Report: Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries, 2002 to 2007, AARP Public Policy Institute Research Report #2008-05 (Washington, DC: AARP), March 2008.
[2] Id.

In contrast, generic prescription drugs are approximately one-third the cost of brand name prescription drugs[3] and, importantly, prices on generic drugs are not rising nearly as quickly as their brand name counterparts. A recent AARP Public Policy Institute study revealed that, on average, manufacturer list prices for the 185 generic prescription drugs most widely used by Medicare beneficiaries have decreased between 2003 and 2007. In 2007, the average annual rate of change in manufacturer prices fell by 9.6 percent, compared to a general inflation rate of 2.9 percent.[4]

Generic drugs have proven to be one of the safest and most effective ways for consumers to lower their prescription drug costs. We encourage our members to use generic drugs whenever possible and their use is steadily increasing. In 1984, generic drugs accounted for 18.6 percent of all retail prescription drugs dispensed in the United States.[5] Now, generic prescription drugs account for two-thirds of all prescriptions dispensed in the United States[6] and 64 percent of prescriptions in the Medicare prescription drug benefit program.[7]

Spiraling drug costs are especially hard for older adults, who are disproportionately affected by chronic disease[8] and more likely to need a chronic medication.[9] When faced with higher drug costs they often skip doses, reduce

[3] National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," 2007. Available online at http://www.nacds.org/wmspage.cfm?parm1=507.
[4] David J. Gross, Stephen W. Schondelmeyer, and Leigh Purvis, Rx Watchdog Report: Trends in Manufacturer Prices of Generic Prescription Drugs Used by Medicare Beneficiaries, 2003 to 2007, AARP Public Policy Institute Research Report #2008-08 (Washington, DC: AARP), May 2008.
[5] Generic Drugs Research Report, AARP Public Policy Institute, publication IB61, May 2003.
[6] Generic Pharmaceutical Association, "Industry Statistics," 2008. Available at www.gphaonline.org/Content/NavigationMenu/AboutGenerics/Statistics/default.htm.
[7] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "October 30, 2008 Part D Symposium Fact Sheet," 2008.
[8] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Healthy Aging: Preserving Function and Improving Quality of Life Among Older Americans," 2008, January 2008.
[9] C. M. Roe, A. M. McNamara, and B. R. Motheral, "Use of Chronic Medications among a Large, Commercially-Insured U.S. Population," Pharmacoepidemiology and Drug Safety11, no. 4: 301–309.

doses, and let prescriptions go unfilled.[10] The result is preventable and expensive hospitalizations and adverse health outcomes.[11]

This occurs far less often for those taking generics. Research has found that people whose initial prescription for a certain therapy was filled with a generic medicine had a 62 percent greater chance of staying on that medicine, and those whose initial prescription was for a preferred brand-name medicine had a 30 percent greater chance of staying on that medicine, versus someone whose initial prescription was for a non-preferred brand-name medicine.[12]

Reverse Payments Harm Consumers

Reverse payments delay market entry of new generics drugs, and thus increase the odds that older Americans will be forced to cut back on or go without needed medicines because of rising cost.

The Protecting Consumer Access to Generic Drugs Act of 2009 is an appropriate remedy to end the problem of reverse payments. First, the legislation would prohibit a patent infringement settlement in which the generic manufacturer receives anything of value in exchange for agreeing not to research, develop, manufacture, market, or sell the product that is the subject of the patent litigation.

[10] J. M. Madden et al., "Cost-Related Medication Nonadherence and Spending on Basic Needs Following Implementation of Medicare Part D," Journal of the American Medical Association 299, no. 26: 1922–1928.
[11] H. Kohl and W. H. Shrank, "Increasing Generic Usage in Medicare Part D: The Role of Government," Journal of the American Geriatric Society 55: 1106–1109.
[12] W. H. Shrank, T. Hoang, S. L. Ettner, P. A. Glassman, K. Nair, D. DeLapp, J. Dirstine, J. Avorn, and S. M. Asch, "The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions," Archives of Internal Medicine 166, no. 3: 332–337.

The legislation provides two common sense safe-harbors:

(1) instances where the only value received by the generic manufacturer is the right to market the drug in question prior to the expiration of the patent; and

(2) instances where the waiver of a patent infringement claim for damages is based on prior marketing of the drug.

In addition, the legislation grants the Federal Trade Commission ("FTC") reasonable authority to establish additional safe-harbors if the FTC finds them "to be in furtherance of market competition and for the benefit of consumers." The legislation also provides that if the generic and name brand manufacturer delay or prohibit competition through reverse payment settlements, the generic manufacturers forfeit the standard 180-day marketing exclusivity period.

These changes in law are sorely needed because when brand and generic pharmaceutical companies engage in conduct that delays market entry of generic drugs, consumers and other health care payers pay higher prices and older Americans are more likely to go without the drugs they need because of cost.

Under current law, the first manufacturer of a generic version of a brand name drug to establish that its drug does not infringe on an existing patent is granted a 180-day period of market exclusivity. After the 180-day period lapses, other generic makers may seek FDA approval to sell their generic versions of the brand name drug, thereby resulting in greater competition and lower drug costs.

Stopping or delaying market entry of the first generic drug thus prevents all other generic drugs from competing, thus extending the brand name manufacturer's market exclusivity. This creates a powerful incentive for branded companies to collude with the first-to-file generic manufacturer to delay market entry of the generic product.

Supporters of reverse payments contend they are necessary to avoid the cost of patent litigation and that to prohibit such payments would chill patent settlements. However, while we recognize that patent litigation can be lengthy and expensive to the parties involved, this cost is dwarfed by the potential savings of timely access to generic drugs for consumers.

Reverse Payments are Counter to Congressional Intent

The Hatch-Waxman Act provides a means for the approval of generic drugs that has greatly increased approval of generics. Although generic drug entry has increased since the Act's passage, its purpose to enable lower cost generic drugs to reach consumers has not been fully realized. Provisions in the law intended to let brand manufacturers – through patent infringement suits – challenge a generic manufacturer's entry into the market have led to reverse payments, which negatively and unfairly impact consumers.

Since the passage of Hatch-Waxman, there have been several well documented instances in which brand manufacturers blocked generic competition by circumventing the Act. Senator Hatch, one of the original co-authors of the Hatch-Waxman Act, has stated that "I find these types of reverse payment collusive agreements appalling. … We did not wish to encourage situations where payments were made to generic firms not to sell generic drugs …."[13]

In 2003, Congress attempted to prevent such evasions of Hatch-Waxman by providing in the Medicare Modernization Act that the Federal Trade Commission ("FTC") be notified of any patent case settlements involving prescription drugs.[14] Unfortunately, the MMA provision did not end reverse payment settlements.

[13] 148 Cong. Rec. S7566 (daily ed. July 20, 2002) (statement of Sen. Hatch).
[14] Medicare Modernization Act, Pub; L. No. 108-173, 117 Stat. 2006.

Litigation Avenues to Address Reverse Payments Have Stalled

Recent court decisions holding that reverse payment agreements do not violate antitrust laws unquestionably have led to an increase of such agreements and hampered the FTC's ability to prevent these abuses. In one case, for example, the FTC found that Schering-Plough, the brand manufacturer of K-Dur, a potassium supplement commonly used to treat heart conditions, violated antitrust laws when it settled litigation with two generic drug manufacturers, Upsher-Smith Laboratories and American Home Products Corp. ("AHP").

Under the challenged agreement, the generic manufacturers agreed to delay market entry of their products in exchange for cash payments of $60 million to Upsher and $15 million to AHP. Schering-Plough appealed the FTC's Order to the Eleventh Circuit, which had just decided another antitrust drug case permitting such settlements, and overruled the FTC decision. The FTC appealed to the Supreme Court; but the Supreme Court declined review of the case, thus ending further avenues for litigation.

In a subsequent case challenging a settlement between the brand and generic makers of tamoxifen, a drug used in the treatment of breast cancer, the Second Circuit held that the challenged agreement was beyond the reach of antitrust laws. The court found that an agreement between a patent holder and an alleged infringer to settle Hatch-Waxman patent litigation would not violate antitrust laws unless, among other things, the patent litigation was a fraud, sham or otherwise baseless.[15] Even though that standard is nearly impossible to meet, the Supreme Court declined to review the Tamoxifen case as well.

[15] In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 208-09 (2d Cir. 2006), cert. denied sub nom. Joblove v. Barr Labs., Inc., _ U.S. _, 127 S. Ct. 3001 (2007).

At present, U.S. Courts of Appeals for the Federal, Second and Eleventh Circuits have rejected antitrust claims challenging reverse payment settlements finding that reverse payment agreements are beyond the reach of antitrust scrutiny – in other words, patent protection trumps Hatch Waxman.[16] The FTC has thus been hampered in its efforts to protect consumers form higher drug prices.

Since the Schering-Plough and Tamoxifen cases, the FTC is reporting a marked increase in the number of questionable settlements; fifty percent of the 2006 settlement agreements between brand and generic manufacturers included some form of payment as well as an agreement to delay generic market entry.[17] With respect to first-filers (e.g., those who enjoy the 180-day period of exclusivity designed to entice non-infringing generics to come to market as soon as possible) 9 out of 11 of the settlements involved a payment by the brand company to the generic manufacturer and a restriction to market entry.

Health Care Reform

Ending these costly patent abuses is essential as we undertake comprehensive health reform efforts to provide all Americans with affordable health care options. AARP is committed to enacting comprehensive health care reform this year because the current health care system costs too much, wastes too much, makes too many mistakes, and provides too little value for far too many consumers. Health care reform will require a series of delivery system reforms – including legislation to prevent market abuses, such as reverse payment, which simply add extra costs to our health care. Health care consumers, and the

[16] In Re Tamoxifen Citrate Antitrust Litigation, 466 F.3d 187 (2d Cir. 2006), cert. denied sub nom. Joblove v. Barr Labs., Inc., _ U.S. _, 127 S. Ct. 3001 (2007); FTC v. Schering Plough Corp., 402 F.3d 1056 (11th Cir. 2005), cert. denied, 126 S.Ct. 2929 (2006); Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1312 (11th Cir. 2003); In Re: Ciprofloxacin Hydrochloride Antitrust Litigation, No. 08-1097 (Fed. Cir. Oct. 18, 2008). In contrast, the Sixth Circuit held that such agreements are per se illegal. In Re CardizemCD Antitrust Litig., 332 F.3D 896 (6th Cir. 2003).

[17] Prepared Statement of the Federal Trade Commission Before the Subcommittee on Commerce, Trade, and Consumer Protection Committee on Energy and Commerce, on Protecting Consumer Access to Generic Drugs: The Benefits of a Legislative Solution to the Anticompetitive Patent Settlements in the Pharmaceutical Industry, May 2, 2007, at 3.

nation, simply can no longer afford these added costs, and we are pleased that the Administration's recent budget document supports efforts to prevent reverse payments.[18] Additional steps to promote and encourage timely access to generic drugs are also necessary to contain costs without compromising quality as we undertake comprehensive health reform.

Since 2006, Medicare Part D has helped millions of older Americans afford medication vital to their health. Unfortunately, because critical legislation to lower drug prices has not been enacted, millions of Americans are struggling to afford their medication. Nearly 20 percent of Medicare beneficiaries under Part D delayed or did not fill a prescription because of costs – higher than any other insured group. For the 3.4 million Americans who fall into the "donut hole", soaring drug prices – especially when their retirement income is shrinking – are putting their health and economic security at risk. AARP believes we must take concrete steps to close the donut hole by lowering drug prices for all Americans, such as through greater use of generics, drug price negotiation, and importation. Prescription drugs are a vital component to improving the health and quality of life for all Americans.

AARP is supporting the Promoting Innovation and Access to Life-Saving Medicine Act, HR 1427. This legislation would create a much-needed pathway for the FDA approval of comparable and generic biologic drugs. We urge Congress to enact this legislation as quickly as possible. We are concerned, however, that unless Congress also prohibits reverse payments, consumers and other health care payers will be denied savings from comparable and generic biologic products, just as currently exists in the traditional prescription drug market.

[18] White House Office of Management and Budget, A New Era of Responsibility: Renewing America's Promise, (Feb. 26, 2009), at 28, available at http://www.whitehouse.gov/omb/assets/fy2010_new_era/A_New_Era_of_Responsibility2.pdf.

Conclusion

AARP strongly supports the Protecting Consumer Access to Generic Drugs Act of 2009. Our members, and all Americans, need Congress to enact this cost saving legislation this year. We are pleased to see the Subcommittee and Members of Congress from both sides of the aisle and both Houses of Congress moving forward on this issue.